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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,860	04/06/2006	Shigeto Kawai	053466-0414	8677

22428 7590 05/07/2008  
FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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05/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,860	<b>Applicant(s)</b> KAWAI ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 15-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/26/07, 2/13/08</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 7, 15, 18, and 21 have been amended.

Claims 8-14 and 20 have been cancelled.

Claims 22 and 23 have been added.

Claims 1-7 remain withdrawn. Claim 23 is withdrawn as not reading on the species of ovarian cancer and breast cancer currently under examination.

2. Claims 15-19, 21, and 22 are under examination.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Accordingly, the claims now receive the priority date of October 10, 2003 for art rejection purposes.

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on September 26, 2007 and February 13, 2008 were filed after the mailing date of the first action on the merits on July 19, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

***Oath/Declaration***

5. The substitute declaration filed on December 19, 2007 has been accepted.

***Objections Withdrawn***

6. The objections to the specification are withdrawn in view of applicant's amendments to the specification.

***Rejections Withdrawn***

7. The rejection of claims 15-21 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims.

8. The rejection of claims 15-21 under 35 U.S.C. 112, second paragraph, as omitting essential method steps is withdrawn in view of applicant's amendment to the claims.

9. The rejection of claims 15-21 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained***

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The rejection of claims 15-19, 21 and newly added claim 22 under 35 U.S.C. 102(b) as being anticipated by Morin, et al. (US PG PUB 2003/0211498, PCT filed April 4, 2001) is maintained.

Applicant's responses filed December 19, 2008 and February 1, 2008 have been carefully considered but are deemed not to be persuasive. The December 19<sup>th</sup> response states that, applicants have amended the method claims to include the administration of the provided antibody. The Office has apparently conceded that this therapeutic method step is not provided in Morin. See Office Action, page 13, lines 3-5. As Morin does not recite every element of the current claims it may not serve as a proper anticipatory reference. In addition, Applicants note that Morin does not describe or suggest the use of an anti-HM1.24 antibody having ADCC activity (see response page 10).

In response to this argument, firstly, the office has not conceded that the administration of an antibody is not provided by Morin. The conclusion statement on page 13 of the previous office action was merely to state why all the limitations of the instant claims could be rejected under Morin in agreement with the 112 rejections.

Regarding the administration of an anti-HM1.24 antibody, as set forth in the previous office action, Morin, et al teach an antibody that specifically recognizes BST-2. The sequence of BST-2 is identical to the instant SEQ ID No. 2. The instant anti-HM1.24 antibody specifically recognizes SEQ ID No. 2. Therefore, the antibody of Morin, et al. would bind to the same protein as the anti-HM1.24 antibody.

Regarding the ADCC activity of the antibody, Morin, et al. do not specifically describe the BST-2 antibody having ADCC activity, however, antibody dependent cell mediated cytotoxicity (ADCC) is an inherent property of an antibody, particularly an IgG antibody. Thus, the antibody of Morin, et al. has ADCC activity.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

### ***Conclusion***

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

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(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

May 5, 2008

/David J Blanchard/  
Primary Examiner, Art Unit 1643